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ENVIRONMENTAL TESTING OF THE XISCAN 1000, PORTABLE
FLUOROSCOPIC AND RADIOGRAPHIC IMAGING SYSTEM

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at high and low high temperatures, transit shock, and vibration. After each environmental insult, performance tests were conducted to determine whether the system continued to meet specifications. Whereas the results showed the system susceptible to damage from temperature extremes and shock, the failure modes were related to design features currently being addressed by the manufacturer or involve only minor mechanical design modification. With these improvements and thoughtful handling, the Xi Scan 1000, packaged in a DEPMEDS standard container, could be expected to survive military field conditions.

DISCLAIMER STATEMENTS

The views, opinions, and/or findings contained in this report are those of the author and should not be construed as official Department of the Army position, policy, or decision, unless so designated by other official documentation. Citations of commercial organizations or trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

The U.S. Army Environmental Hygiene Agency conducted a radiation protection survey before testing was initiated to ensure safety and regulatory compliance of the Xi Scan 1000 X-RAY SYSTEM. The Fort Detrick Radiation Protection Officer (RPO) certified the shielded X-ray test facility in accordance with (IAW) Army Regulation (AR) 40-5 and 385-11. The X-ray system performance test protocol used in this study was approved by the USAG Ionizing Radiation Control Committee. Preplacement and termination medical examinations of test personnel were conducted and documented IAW AR 40-14.



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ABSTRACT

The Xi Scan 1000, Portable Fluoroscopic and Radiographic Imaging System, (Xi Tech, Inc., Windsor Locks, CT), is a hand-held unit which can be configured as a 2.6 inch, direct view fluoroscope or a standard X-ray machine for 8x10" film. This study used the "System 3" package including a C-arm, cassette tray, image intensifier, and rechargeable battery power supply which weigh 30 pounds in the commercial carrying case. Although this system could not replace existing military radiography equipment, it could enhance current capability. The fluoroscope would benefit surgeons during procedures in far-forward facilities and it could provide instant feedback to other medical personnel as to the severity of common injuries. Although the Xi Scan 1000 appears robust, it was not designed for harsh environmental conditions. For this study, a container was procured that meets the Deployable Medical Systems (DEPMEDS) packaging standard (MIL-D-42048). With this container, the system was subjected to environmental tests IAW MIL-STD-810E, Environmental Test Methods and Engineering Guidelines, to include: storage and operation at high and low temperatures, transit shock, and vibration. After each environmental insult, performance tests were conducted to determine whether the system continued to meet specifications. Whereas the results showed the system susceptible to damage from temperature extremes and shock, the failure modes were related to design features currently being addressed by the manufacturer or involve only minor mechanical design modification. With these improvements and thoughtful handling, the Xi Scan 1000, packaged in a DEPMEDS standard container, could be expected to survive military field conditions.

INTRODUCTION

The Xi Scan 1000, Portable Fluoroscopic and Radiographic Imaging System, (Xi Tech, Inc., Windsor Locks, CT), is a hand-held unit designed primarily for podiatric, pediatric, sports medicine, and veterinary practitioners. The complete system consists of a C-arm assembly, X-ray cassette tray, image intensifier with beam limiting device, video monitor, thermal printer, digital image storage device, mobile stand, and rechargeable battery power supply. It can be purchased in several configuration packages that include various subsets of the complete system. This study utilized the "System 3" package which includes the C-arm, cassette tray, image intensifier, and rechargeable battery power supply which weigh 30 pounds in the commercial carrying case. The system's modular design allows configuration as a 2.6 inch field of view fluoroscope (see Figure 1) or a standard X-ray machine (see Figure 2) with 8 by 10 inch film capacity. In either mode, the system is capable of imaging the extremities only. The system can operate continuously from line power (110 VAC) or from a NiCad battery pack which supports two hours of continuous fluoroscopy or up to 100 radiographic exposures.

Although the Xi Scan 1000 is not a replacement for existing radiography equipment in the field, it has features and characteristics that could enhance current military medical capability and efficiency. The direct view fluoroscope could provide feedback to far-forward medical personnel as to the severity of common injuries. The system could also provide field surgeons with fluoroscopic imaging during surgical procedures in far-forward medical facilities.

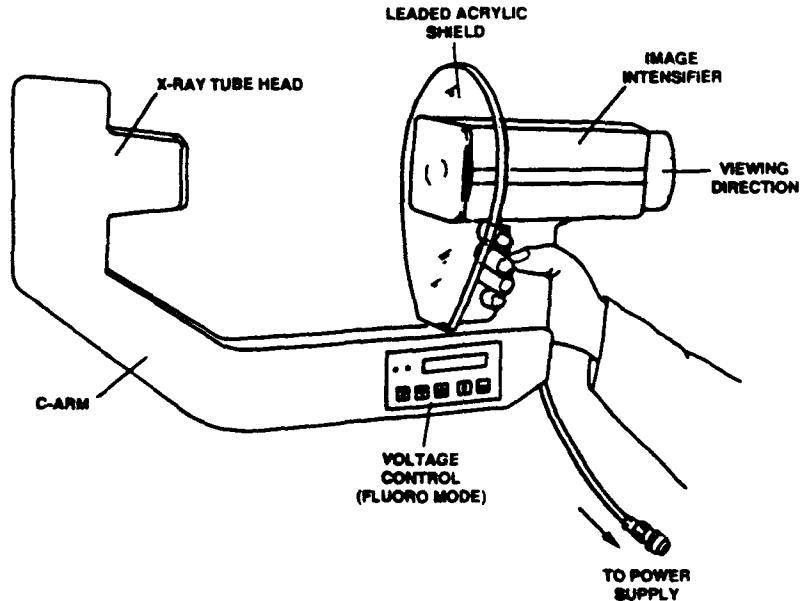


FIGURE 1: XI SCAN 1000 SYSTEM CONFIGURED FOR FLUOROSCOPY

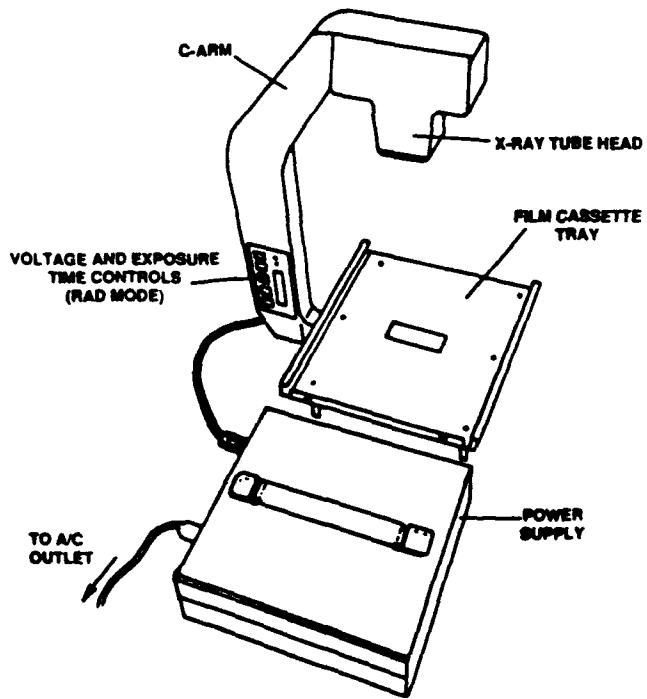


FIGURE 2: XI SCAN 1000 SYSTEM CONFIGURED FOR RADIOGRAPHY

Although the system seems inherently robust, it was not designed to withstand the extremes of environmental conditions experienced in the field; nor has it been tested to determine its susceptibility to damage. Moreover, the commercial packaging for the Xi Scan 1000 was not designed to meet military specifications or to withstand handling, storage and transport, or deployment in a military field environment. Environmental testing was designed to determine if the commercially available unit is sufficiently rugged to withstand military field conditions without significant design changes or extraordinary packaging measures.

This report presents a quantitative evaluation of the ability of the Xi Scan 1000 to withstand the rigors of storage, transport, and operation, in a military field environment IAW MIL-STD-810E, Environmental Test Methods and Engineering Guidelines, based on its potential life cycle history and mission profile.

METHODS AND MATERIALS

A Xi Scan 1000 X-ray system was provided to this laboratory on a no cost loan agreement by Dow Corning Wright, New England Associates, Inc. (Manchester, NH), absolving the U.S. Government, the U.S. Army and this Laboratory from responsibility for damage that might occur to the system during testing. The U.S. Army Environmental Hygiene Agency conducted a radiation protection survey of the Xi Scan 1000 to ensure the safety of test personnel and compliance with manufacturer published specifications and applicable military and federal regulations. The Fort Detrick Radiation

Protection Officer conducted a survey of the X-ray test facility used for this study IAW AR 40-5 and 385-11 and certified it to provide adequate shielding to surrounding areas. Preplacement and termination medical examinations of test personnel were conducted and documented IAW AR 40-14. The X-ray system performance test protocol, designed to evaluate the condition of the X-ray system before, during, and after each environmental challenge, was approved by the U.S. Army Garrison Ionizing Radiation Control Committee on 26 FEB 1991. Although the performance testing did not constitute a complete radiation protection survey, it provided adequate data to conclude whether or not the system continued to meet performance specifications. All radiation output (mR and mR/hr) measurements were made using an MDH X-ray Monitor (model 1015, serial number 2141, RadCal Corp., Monrovia, CA).

To evaluate system performance in the standard radiographic mode, two standard quality assurance tests (exposure reproducibility and exposure linearity) were conducted. Reproducibility of exposure was determined by measuring radiation output (mR) with the X-ray system voltage set to 65 kVp at three different exposure time settings (0.25, 0.75, and 1.5 sec.). Three measurements were made at each time setting and averaged. The unit passed the exposure reproducibility test if individual output measurements at a given exposure time fell within a range of 95% and 105% of the calculated average at the same time setting (Hendee, 1979). Exposure linearity is used to determine if radiation output is constant for a given mAs value regardless of the mA/time station employed (Hendee, 1979). Title 21 Code of Federal Regulations 1020.31 (c)(1) requires that the ratio of mR/mAs for any two consecutive tube current settings at a given kVp differ by no more than 0.10 times their sum.

for exposure to be considered linear. Although exposure linearity is normally calculated for radiography machines with adjustable X-ray tube current levels, it was used to indicate changes in radiation output per unit time for the fixed current X1 Scan 1000. A single measurement of radiation output at 45 and 55 kVp was made at three exposure time settings (0.25, 0.75, and 1.5 sec.). The ratios of mR/mAs were calculated using the previously calculated average exposure at 65 kVp and individual exposures at 45 and 55 kVp. Exposure linearity was determined by comparing the differences and sums of mR/mAs values at consecutive time station settings.

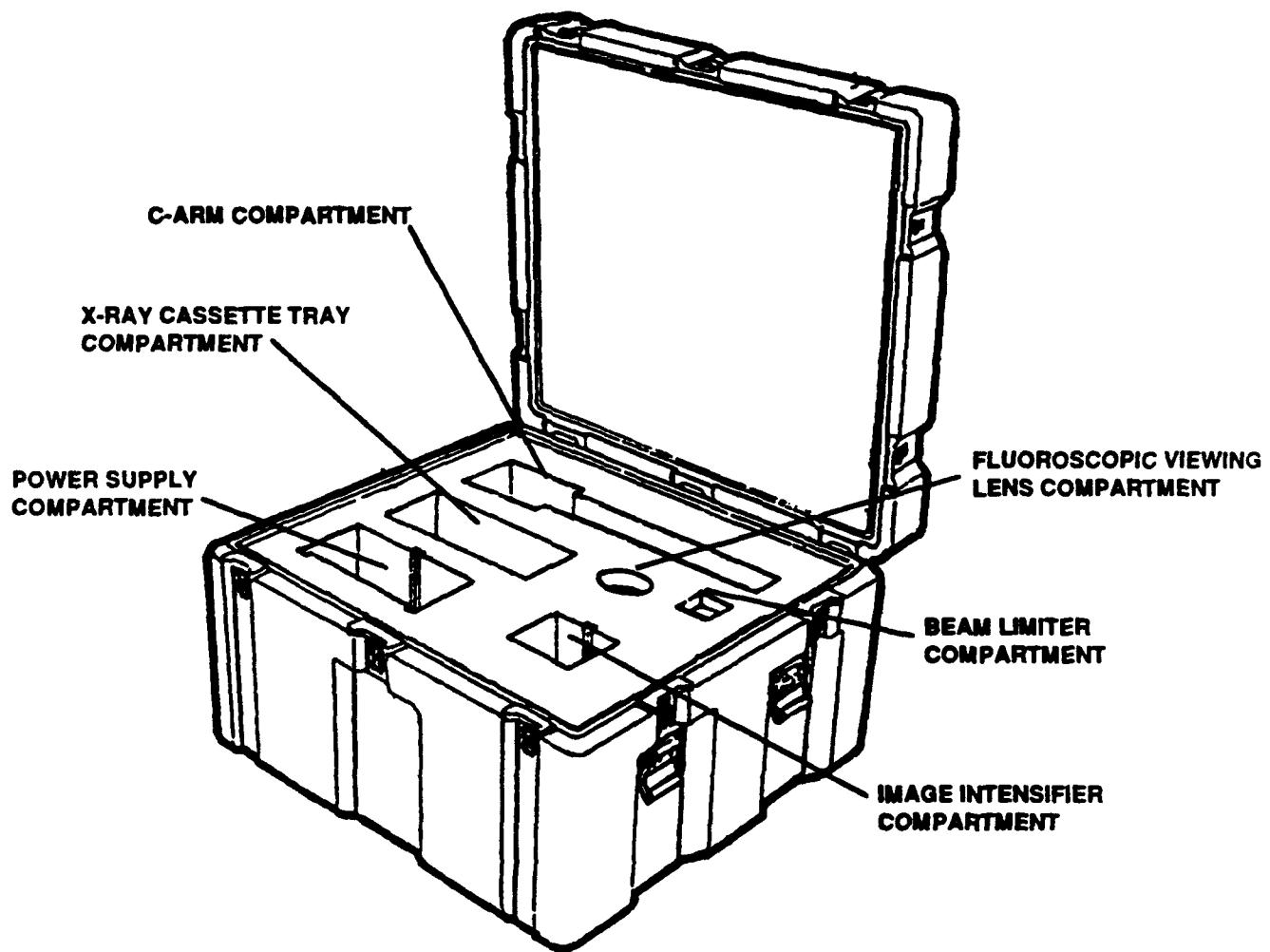
To evaluate performance in the fluoroscopic mode, three standard quality assurance tests were conducted. To determine consistency of output by the X-ray tube, the maximum exposure rate (mR/hr at 65 kVp) was measured for comparison to baseline data. To determine if the image intensifier was functioning properly, a low contrast resolution test was conducted using a 0.03 inch thick aluminum plate with two rows of four holes (0.25, 0.188, 0.125, and 0.0625 diameter) backed by a 0.75 inch thick solid aluminum attenuation plate. This low contrast resolution phantom was imaged in fluoroscopic mode before and after environmental tests, and the size of the smallest perceptible hole pair was recorded (Hendee, 1979). Finally, a high contrast resolution test was conducted using a high contrast resolution test tool (model number 07-619, Victoreen, Inc., Cleveland, OH). This tool consisted of eight patterns of copper wire mesh from 30 to 100 lines/inch arranged in a pie shape. The finest mesh resolvable by the system was recorded before and after environmental testing. To ensure the results were

not influenced by variations in operator eyesight, one individual conducted this test.

The environmental test regime included a series of tests performed in accordance with MIL-STD-810E, Environmental Test Methods and Engineering Guidelines, Methods 501.2 (I&II), 502.2 (I&II), 514.3 (II), and 516.3 (IV). The tests were designed to simulate the type and severity of handling, transportation, and climatic conditions associated with the potential life cycle history of the device. The environmental test conditions included high temperature storage and operation, low temperature storage and operation, transit shock, and vibration.

To optimize protection against environmental insult, a shipping container meeting the Deployable Medical Systems (DEPMEDS) packaging standard (MIL-D-42048) was procured for the basic Xi Scan 1000 (see Figure 3). The rotationally molded polyethylene container (Hardigg Industries, Inc., South Deerfield, MA) was 27 inches long by 26 inches wide by 14.8 inches high, weighed 30 pounds, and contained custom fabricated polyurethane foam cushioning.

For low temperature storage (Method 502.2, Procedure I), the packaged Xi Scan 1000 was placed in the environmental chamber at -60°F for 24 hours. It was removed, allowed to equilibrate to 77°F, and subjected to the performance tests described previously. The rechargeable batteries were removed from the power supply during cold storage, kept at 77°F and replaced before performance testing. For low temperature operation (Method 502.2, Procedure II), the unpackaged unit was placed in the environmental chamber at 40°F for three hours, rapidly moved to the X-ray test facility, and evaluated. The



**FIGURE 3: ROTOMOLDED POLYETHYLENE SHIPPING CONTAINER
(HARDIGG INDUSTRIES, INC., SOUTH DEERFIELD, MA.) FOR THE XI SCAN
1000 X-RAY SYSTEM**

unit could not be tested inside the environmental chamber because it was not certified for X-ray testing.

For high temperature storage (Method 501.2, Procedure I), the packaged Xi Scan 1000 was subjected to seven, 24 hour diurnal cycles from 95 to 160°F under climatic category "Hot" for "Induced Conditions" (AR 70-38, 1979). The unit was allowed to equilibrate to 77°F before undergoing performance testing. For high temperature operation (Method 501.2, Procedure II), the unpackaged unit was placed in the environmental chamber at 120°F for three hours, rapidly moved to the X-ray test facility, and evaluated.

The transit shock test (Method 516.3, Procedure IV), involves dropping a packaged test item on each of the 26 corners, faces, and edges, and requires at least five different test units. With only one Xi Scan 1000 available, this test was abbreviated. Each corner, face, and edge of the shipping container was assigned a number between 1 and 26. Five random numbers in this sequence were generated on a computer, and the packaged unit was dropped on the five corresponding points from a height of 48 inches onto a two inch thick plywood surface backed by concrete. After all five drops, the unit was subjected to performance testing.

For vibration testing (Method 514.3, Procedure II, Category III; loose cargo transport), the packaged unit was subjected to a one inch double-amplitude orbital path at 250 revolutions per minute on a package tester (model 400SLVMCHI, serial number 5200124, LAB Corporation, Skaneateles, NY). After three hours of vibration testing, the unit was subjected to performance testing.

RESULTS

BASELINE TESTING

Because of electrical and mechanical problems, four Xi Scan 1000 units were used to complete the battery of tests. Table 1 lists the four units that were used and Tables 2, 5, 9, and 10 list the baseline data that were collected prior to testing. Baseline radiographic output for all units was both linear and reproducible except in one circumstance, and fluoroscopic performance was impressive for a low-power system.

LOW TEMPERATURE STORAGE

Low temperature storage (see Table 3) had no significant effect on linearity or reproducibility of the system output in the radiographic mode. Fluoroscopy test results were nearly identical to baseline. The only observed effect of low temperature storage on unit #1 was a trace of transformer oil that seeped from the X-ray tube housing.

LOW TEMPERATURE OPERATION

Low temperature operation for unit #1 resulted in erratic if not random output in the radiographic mode at 65 kVp (see Table 4). The remainder of the test sequence was aborted. Once equilibrated back to 77°F, however, measured output at 55 kVp and 45 kVp for unit #1 stabilized and was consistent with baseline data (see Table 4). In light of this fact, the environmental test plan was continued using unit #1. Concerned at the erratic output during low temperature operation, the manufacturer provided a second unit, (unit #2) to be tested for low temperature operation only. The baseline data for unit #2 at 65 kVp and 0.25 seconds proved non-reproducible (see Table 5). There is

however, one suspicious output measurement, that if omitted, makes the overall data set reproducible. Low temperature operational tests (see Table 6) on unit #2 were limited to reproducibility in the radiographic mode. Output during low temperature operation was reproducible and consistent with baseline data.

HIGH TEMPERATURE OPERATION

During high temperature operation (see Table 7), unit #1 exhibited no degradation in output in either radiological or fluoroscopic modes. The only change in operation was a slight flickering of the digital display and an audible signal which finally resulted in a low battery indication. The battery was charged overnight and testing continued.

HIGH TEMPERATURE STORAGE

The high temperature storage test resulted in additional transformer oil seepage from the tubehead housing. The resulting output (see Table 8), however, in the radiological mode was both linear and reproducible. When the unit was configured in the fluoroscopic mode, one output measurement was recorded before the digital display read "CALL SERVICE". An inspection of the device revealed two blown fuses, which were replaced, but blew out again immediately on power-up. The remainder of the fluoroscopy tests were aborted and the unit was returned to the manufacturer for repair, but a different unit was returned for continued testing (unit #3).

TRANSIT SHOCK

The transit shock (i.e. drop) test performed on unit #3 resulted in no apparent physical damage, but no radiation output could be measured during performance testing. The manufacturer determined the problem was related to

the battery tie-down mechanism within the power supply and noted that unit #3 contained an older design mechanism. Rather than replace the older design battery tie-down mechanism in unit #3, the manufacturer chose to return a different unit that already included the newer design (unit #4). As noted in Table 1, unit #4 was actually unit #1 with a different power supply. A new set of baseline data, limited to linearity and reproducibility in the radiographic mode were collected (see Table 10). Although baseline data analysis showed one non-linear sequence of measurements at 55 kVp, the radiation output (mR) was not sufficiently different from previous tests to cause suspicion at the time. Unit #4 was subjected to the transit shock test, after which the power supply was opened for inspection of the battery tie-down mechanism. The battery tie-down straps were sheared during the test. Since this appeared to cause no other physical damage, the performance tests were conducted. The output proved both linear and reproducible for all measurements in the radiographic mode (see Table 11).

VIBRATION

Vibration testing was conducted on unit #4, resulting in no degradation of output performance (see Table 12). Output in the radiographic mode was both linear and reproducible. Fluoroscopic test results were consistent with baseline for unit #1 (see Table 2).

DISCUSSION

Although environmental testing of the Xi Scan 1000 caused several system failures, the overall results were favorable. The system proved to be relatively robust for a commercial X-ray system.

The erratic output of unit #1 during low temperature (40°F) operational tests was not explained. At no time, however, was there any indication that the patient or user would be exposed to high levels of radiation. Moreover, unit #2 showed no performance problems in low temperature operation, suggesting the problem was unique to unit #1. Further testing of different units in low temperature operation could substantiate this possibility. The manufacturer mentioned similar problems during several of their own high temperature operational tests, which were attributed to temperature sensitive high voltage components. A company representative reported that replacement of these components is planned for future models.

The transformer oil seepage from unit #1 during both low and high temperature storage tests resulted from the inability of the internal expansion bellows to compensate for the large change in oil volume. This could result from one of two design features. First, the expansion bellows may be expanding and contracting to its limits before adequate oil volume compensation is achieved, thus causing internal pressure to rise above the capability of the housing seal. Second, the expansion bellows may not be sufficiently compliant at its extremes, and internal pressure breaks the housing seal before further expansion or contraction can take place. The failure of unit #1 during fluoroscopy tests after high temperature storage was

probably a result of the low temperature storage test. Extremely low temperatures caused the oil to contract, and air was allowed into the housing by one of the mechanisms described above. The air bubble inside the tube housing caused no problems until migrating to a location that allowed high voltage arcing between the filament and the housing. This failure was not unexpected given the ambient conditions in which the unit was designed to operate. Should this type failure occur in the field, the unit would have to be returned to the manufacturer for repair. The manufacturer noted, however, that the tube housing seal design was being improved in future models.

During the transit shock test on the first unit, the battery tie-downs broke, causing internal damage to the power supply, requiring repair by the manufacturer. In a transit shock test on a second unit, a set of improved battery tie-downs also broke, but the power supply was not otherwise damaged. An evaluation of the combined power supply and battery pack suggests that the probability of damage as a result of impact is high. This is particularly important if the system were used in airborne operations. In addition, removal or replacement of the batteries from the combined power supply and battery pack of the Xi Scan 1000 is difficult and labor intensive. On a positive note, there was no indication that the tube head assembly or the optics in the image intensifier tube were vulnerable to damage from shock or vibration.

CONCLUSIONS AND RECOMMENDATIONS

The X1 Scan 1000 was found susceptible to damage from environmental conditions such as temperature extremes and shock. The failure modes, however, were related to the design features that are currently being addressed by the manufacturer or involve minor mechanical design modification. Given that X-ray systems are inherently delicate instruments and require special handling, the severity of the problems identified during environmental testing was less than expected.

Instability during low temperature operation of unit #1 was probably an isolated, equipment specific incident. If it was the same intermittent problem the manufacturer has seen in high temperature operation, it will be corrected on future models. The issue of transformer oil seeping from the X-ray tube housing in extreme temperatures is being addressed by the manufacturer. The battery tie-down mechanism must be improved before the unit could be expected to withstand handling, transport, or deployment in a military field environment. A re-design of the power supply and battery pack unit could accomplish that objective and provide easier access for removal or replacement of the batteries.

Given these improvements and thoughtful handling, the X1 Scan 1000, packaged in a DEPMEDS standard container, could be expected to withstand the environmental challenge of military field conditions.

TABLE 1: SERIAL NUMBERS OF INDIVIDUAL XI SCAN 1000 X-RAY UNITS USED DURING ENVIRONMENTAL TESTING

	UNIT #1	UNIT #2	UNIT #3	UNIT #4
C-ARM POWER SUPPLY BEAM LIMITER IMAGE INTENSIFIER CASSETTE HOLDER	CA900626.001 CB900626.001 CP900626.001 CI 900806.002 CC900629.001	CA900615.002 CB900322.001 CP900615.001 CI 900615.002 CC900522.001	CA890907.001 CB900817.014 AP890907.001 CI 900501.001 AC890907.001	CA900626.001 CB900614.001 CP900626.001 CI 900806.002 CC900629.001
COMMENTS	Erratic operation at 40°F. Failed after high temperature storage test, returned for repair.	Tested only for operation at 40°F.	Replacement for unit # 1. Failed after transit shock, returned for repair.	Replacement for unit # 3. Used for transit shock and vibration. NOTE: Same as unit #1 except power supply.

TABLE 2: XI SCAN 1000 BASELINE DATA (Unit #1)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	20.2	59.5	117.0						
	20.6	59.4	117.0	14.4	42.9	84.6	8.9	25.7	50.9
Average mR	20.7	59.5	117.0						
* .95 Avg mR - 1.05 Avg mR	19.6 - 21.7	56.6 - 62.5	111.2 - 122.9						
mR/mAs	82.7	79.4	78.0	57.6	57.2	56.4	35.3	34.3	33.9
† Linearity		0.02	0.009		0.003	0.007		0.019	0.005
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	22.1			0.125			60		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

TABLE 3 : XI SCAN 1000 LOW TEMPERATURE STORAGE - MIL-STD-810E,
502.2 (I), (Unit #1)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	21.6	56.4	121.0						
	22.3	60.5	121.0	15.9	43.6	85.3	9.6	26.1	50.6
	21.8	60.7	122.0						
Average mR	21.9	59.2	121.3						
* .95 Avg mR - 1.05 Avg mR	20.8 - 23.0	56.2 - 62.2	115.3 - 127.4						
mR/mAs	87.6	78.9	80.9	63.6	58.1	56.9	38.4	34.8	33.7
† Linearity	0.052	-0.012		0.045	0.011		0.049	0.016	
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	20.8			0.125			60		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

TABLE 4 : XI SCAN 1000 LOW TEMPERATURE OPERATION - MIL-STD-810E,
502.2 (II), (Unit #1)

kVp	65			55**			45**		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	19.8	1.41	3.34						
	1.03	2.05	34.5	14.1	39.2	78.0	8.28	23.7	47.3
	1.27	2.34	4.12						
Average mR	7.4	1.9	14.0						
* .95 Avg mR - 1.05 Avg mR	7.0 - 7.8	1.8 - 2.0	13.3 - 14.7						
mR/mAs	29.6	2.5	9.3	56.4	52.3	52.0	33.1	31.6	31.5
† Linearity	0.84	-0.58		0.038	0.003		0.023	0.002	
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	***			***			***		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

** Measurements at 55 and 45 kVp are after equilibration to 77°F.

*** Test sequence aborted due to erratic output and system warning.

**TABLE 5: XI SCAN 1000 BASELINE
DATA (Unit #2)**

kVp	65	55	45
Exposure time (seconds)	0.25	0.75	1.5
Radiation Output (mR)	17.5 [†]	37.0	42.9
	21.4	38.9	44.1
	21.1	39.3	44.1
	20.0	38.4	43.7
Average mR	20.0	38.4	43.7
* .95 Avg mR - 1.05 Avg mR	19.0 - 21.0	36.5 - 40.3	41.5 - 45.9

* Individual output measurements must fall within this range for output to be considered reproducible.

[†] Suspect data; Omitting this point makes
 $\text{Avg mR} = 20.83$; $.95 - 1.05 \text{ Avg mR} = 19.8 - 21.9$

**TABLE 6: XI SCAN 1000
LOW TEMPERATURE OPERATION,
MIL-STD-810E, 502.2(II), (Unit #2)**

kVp	65	55	45
Exposure time (seconds)	0.25	0.75	1.5
Radiation Output (mR)	22.1	35.5	35.8
	22.2	36.0	38.7
	22.0	35.8	38.6
	22.1	35.7	37.7
Average mR	22.1	35.8	37.7
* .95 Avg mR - 1.05 Avg mR	21.0 - 23.2	33.7 - 37.3	35.8 - 39.6

* Individual output measurements must fall within this range for output to be considered reproducible.

TABLE 7: XI SCAN 1000 HIGH TEMPERATURE OPERATION - MIL-STD-810E, 501.2 (II), (Unit #1)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	19.3	58.6	117.0						
	19.4	57.9	117.0	14.5	41.9	84.5	8.9	25.0	48.9
	19.2	57.9	117.0						
Average mR	19.3	58.1	117.0						
* .95 Avg mR - 1.05 Avg mR	18.3 - 20.3	55.2 - 61.0	111.2 - 122.9						
mR/mAs	77.2	77.5	78.0	58.0	55.9	56.3	35.8	33.3	32.6
† Linearity	-0.002	-0.003		0.019	-0.004		0.035	0.011	
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	20.3			0.125			60		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

TABLE 8: XI SCAN 1000 HIGH TEMPERATURE STORAGE - MIL-STD-810E, 501.2 (I), (Unit #1)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	21.1	59.6	120.0						
	21.6	60.8	119.0	15.4	44.0	88.0	9.5	26.6	52.5
	21.3	60.4	122.0						
Average mR	21.3	60.3	120.3						
* .95 Avg mR - 1.05 Avg mR	20.3 - 22.4	57.3 - 63.3	114.3 - 126.4						
mR/mAs	85.3	80.4	80.2	61.6	58.7	58.7	38.0	35.5	35.0
† Linearity	0.030	0.001		0.024	0.000		0.034	0.007	
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	21.1			**			**		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

** Unit failed before fluoroscopy tests were complete.

TABLE 9: XI SCAN 1000 BASELINE DATA (Unit #3**)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	24.1	67.0	125.0						
	24.1	66.7	122.0	19.2	56.4	109.0	11.2	31.6	61.9
	23.0	66.2	116.0						
Average mR	23.7	66.6	121.0						
* .95 Avg mR - 1.05 Avg mR	22.5 - 24.9	63.3 - 70.0	115.0 - 127.1						
mR/mAs	94.9	88.8	80.7	76.8	75.2	72.7	44.8	42.1	41.3
† Linearity		0.033	0.048		0.011	0.017		0.031	0.010
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	***			***			***		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

** No post-test data for this unit.

*** No fluoroscopy baseline data taken.

TABLE 10: XI SCAN 1000 BASELINE DATA (Unit #4)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	21.1	55.5	106.0						
	20.6	55.0	105.0	15.1	35.9	72.5	8.9	22.5	42.9
	21.5	55.3	105.0						
Average mR	21.1	55.3	105.3						
* .95 Avg mR - 1.05 Avg mR	20.0 - 22.1	52.5 - 58.0	100.1 - 110.6						
mR/mAs	84.3	73.7	70.2	60.4	47.9	48.3	35.7	30.0	28.6
† Linearity		0.067	0.024		0.116 ^{††}	-0.005		0.086	0.016
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	**			**			**		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

** No fluoroscopy baseline data taken.

†† Non-linear result.

TABLE 11: XI SCAN 1000 TRANSIT SHOCK - MIL-STD-810E, 516.3 (IV), (Unit #4)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	19.9	52.8	101.0						
	20.1	51.7	101.0	14.3	36.6	70.4	8.3	22.1	41.6
	20.2	52.2	101.0						
Average mR	20.1	52.2	101.0						
* .95 Avg mR - 1.05 Avg mR	19.1 - 21.1	49.6 - 54.8	96.0 - 106.1						
mR/mAs	80.3	69.6	67.3	57.2	48.8	46.9	33.3	29.5	27.7
† Linearity		0.071	0.017		0.079	0.019		0.061	0.030
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	**			**			**		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

** No Fluoroscopy data taken.

TABLE 12: XI SCAN 1000 VIBRATION - MIL-STD-810E, 514.3 (II), CATEGORY III (Unit #4)

kVp	65			55			45		
Exposure time (seconds)	0.25	0.75	1.5	0.25	0.75	1.5	0.25	0.75	1.5
Radiation Output (mR)	19.1	51.9	100.0						
	19.6	52.3	100.0	13.6	35.3	68.4	7.7	21.1	41.0
	19.7	52.5	98.1						
Average mR	19.5	52.2	99.4						
* .95 Avg mR - 1.05 Avg mR	18.5 - 20.4	49.6 - 54.8	94.4 - 104.3						
mR/mAs	77.9	69.6	66.2	54.4	47.1	45.6	30.8	28.1	27.3
† Linearity		0.056	0.025		0.072	0.016		0.045	0.014
Fluoroscopy Tests	Maximum Exposure Rate (mR/hr)			Smallest Hole Perceptible (in)			Finest Mesh Perceptible		
	17.9			0.125			60		

* Individual output measurements must fall within this range for output to be considered reproducible.

† Must be < 0.10 for output to be considered linear. Calculated as: $\frac{mR/mAs_1 - mR/mAs_2}{mR/mAs_1 + mR/mAs_2}$

REFERENCES

Hodge, J.W. and G.E. Toms, Jr. 1991. Xi Scan 1000 Radiographic and Fluoroscopic Imaging System, Test Report. U.S. Army Biomedical Research and Development Laboratory, MR 14-91, Fort Detrick, Frederick, MD, 21702-5010.

1991. Radiation Protection Study No. 28-43-0682-91, Portable Radiographic/Fluoroscopic X-ray System. U.S. Army Environmental Hygiene Agency, Aberdeen Proving Ground, MD, 21010-6422.

1991. Memorandum for See Distribution, Subject: Minutes of the U.S. Army Garrison Ionizing Radiation Control Committee (IRCC), HSHD-SHE (385-11), 7 March.

1990. Preventive Medicine. Army Regulation 40-5.

1989. Environmental Test Methods and Engineering Guidelines. Military Standard MIL-STD-810E.

1987. Deployable Medical Systems, General Requirements For. Military Specification MIL-D-42048.

1982. Control and Recording Procedures for Exposure to Ionizing Radiation and Radioactive Materials. Army Regulation 40-14.

1981. Management and Control of Diagnostic X-Ray, Therapeutic X-Ray, and Gamma-Beam Equipment. U.S. Army Technical Bulletin Medical 521.

1980. Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety). Army Regulation 385-11.

1979. Research, Development, Test and Evaluation of Materiel for Extreme Climatic Conditions. Army Regulation 70-38.

Hendee, W.R. and R.P. Rossi. 1979. Quality Assurance for Fluoroscopic X-Ray Units and Associated Equipment. U.S. Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, FDA 80-8095, Rockville, MD.

Hendee, W.R. and R.P. Rossi. 1979. Quality Assurance for Radiographic X-Ray Units and Associated Equipment. U.S. Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, FDA 79-8094, Rockville, MD.

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